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# An Overnight Comparison of Core Temperature Using a Rectal Probe and a Radio Pill

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DEPARTMENT OF NATIONAL DEFENCE – CANADA

# EXECUTIVE SUMMARY

**Introduction.** We are about to undertake a major fatigue countermeasure study in support of our Air Transport Aircrews. Because this study will involve early circadian sleep periods and medications, both of which can circadian phase advances, we need to measure body core temperature in order to be able to determine the extent of any circadian phase shifts. The standard technique for measuring core temperature in this institute is the rectal probe. The rectal probe can be uncomfortable and could impact on the sleep quality of our subjects. In an effort to avoid impacting on the sleep quality of our subjects during the fatigue countermeasure study, we wish to use a radio pill technique to measure core temperature. Earlier versions of radio pills and their associated data loggers, at least in some studies, were not as reliable as the rectal probe. This current effort is to assess whether or not the latest version of radio pill technology is sensitive enough to discriminate the circadian temperature trough.

**Metods.** Resting core temperatures provided by radio pill and by rectal probe, were monitored in 7 subjects over 15 hours, including the overnight period. To assess the impact of drinking fluids on radio pill core temperature, several trials were run where 2 subjects drank 250 mL of each of cold water (7.1°C), body temperature water (37.0°C), and hot water (60.0°C). ). **Results & Discussion.** The data from the 7 subjects indicates that there was no significant difference in core temperature provided by the rectal probe versus the core temperature provided by the radio pill. However, we found that drinking hot or cold drinks can cause errors in radio pill core temperature. **Conclusions.** This latest version of the radio pill technology appears to provide an accurate alternative to rectal probes, and is sensitive enough to measure the circadian core temperature trough. If subjects must drink during an experimental session, and if it is important to avoid drinking-induced perturbations of core temperature provided by radio pill during such sessions, subjects should only drink body temperature fluids.

## ABSTRACT

**Introduction.** Previous efforts to record core temperature with radio pills produced consistent results showing that core temperature provided by radio pill tended to be lower than that provided by rectal probe by about 0.5°C to 0.6°C. Part of this temperature difference (about 0.2°C to 0.3°C) was thought to be due to the fact that as the radio pill courses through the gut, it passes through areas of differing vasculature, perfusion, and metabolism which result in slightly varying local core temperatures. The studies which produced these results were generally monitoring subjects for 3 to 4 hours. There was very little information as to the efficacy of the radio pill with respect to its ability to track the daily circadian temperature trough, which is a pre-requisite to successful work in the domain of circadian rhythms. This study is an attempt to evaluate the radio pill against the rectal probe, over 15 hours, in order to determine whether or not the radio pill is sensitive enough to discriminate the circadian temperature trough. **Methods.** Resting core temperatures provided by radio pill and by rectal probe, were monitored in 7 subjects over 15 hours, including the overnight period. The rectal probe and its data logger were the standard units used in this laboratory. The radio pill and its data logger were recently improved units lent to us by their manufacturers for evaluation. The data loggers for each of the rectal probes and the radio pills were set to collect data every minute. The subjects wore the data loggers (for each of the pill and probe) on a belt throughout the 15 hour time block. The data from the 7 subjects were submitted to a double repeated-measures analysis of variance (anova). To partition the variability of radio pill output due to any inherent variability of the pill versus variability due to transit through different areas of the GI tract, a pill and a probe were immersed in a water bath at 35°C. The bath was then heated to approximately 39.7°C over more than 3 hours, at which point, the heater was turned off and the water bath allowed to cool passively over almost another 2 hours. To assess the impact of drinking fluids on radio pill core temperature, several trials were run where 2 subjects drank 250 mL of each of cold water (7.1°C), body temperature water (37.0°C), and hot water (60.0°C). **Results & Discussion.** The comparison of the radio pill and the rectal probe in the water bath indicate that there is no variability inherent in the radio pill itself and no real difference in temperature measured by the radio pill and the rectal probe when they are in the same micro-environment. The anova for the core temperature data from the 7 subjects indicates there was no main effect of *sensor* (pill vs. probe, $p=0.633$) but the main effect of *time* was significant ($p=0.001$). The *sensor x time* interaction was not significant ($p=0.093$). The main effect of *time* was significant because the night time temperatures (during the circadian trough) were lower than the day time temperatures. While the *sensor x time* interaction was not significant it showed a tendency towards significance because of the drinking-induced drop in radio pill temperature during the supper and early evening hours. It was noted that drinking of either hot or cold drinks can cause gross errors in core temperature as measured by radio pill. **Conclusions.** This latest version of the radio pill technology appears to provide an accurate alternative to rectal probes, and is sensitive enough to measure the circadian core temperature trough. If subjects must drink during an experimental session, and if it is important to avoid drinking-induced perturbations of core temperature provided by radio pill during such sessions, subjects should only drink body temperature fluids.

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# INTRODUCTION

In 1983, using radio pills and a data logger built in-house (DCIEM), Livingstone et al. (2) compared core temperatures measured by rectal thermistor (Tre), esophageal thermistor (Tes), and radio pill for gastro-intestinal (GI) tract temperature (Tpill). Their study looked at the effect of cold and wind (-32°C and 11 km/hr wind) on various measurement sites. They found that these three core temperature modalities (Tre, Tes, and Tpill), gave comparable and consistent measurements within ±0.5°C of each other.

Recently there has been renewed interest in the use of radio pill technology for monitoring core temperature in human subjects (3,4). In 1993, Sparling et al. (4) compared core temperatures using rectal thermistors, and radio pills together with an ambulatory recorder (CoreTemp, COR-100) manufactured by Human Technologies (HTI) of St. Petersburg, FL. They found that core temperature measured in the GI tract by radio pill was consistently lower than the corresponding temperature measured by a rectal thermistor, during each of rest (0.6$^0$C), exercise (0.9 – 1.0$^0$C), and recovery from exercise (1.1$^0$C).

More recently. Obrien et al. (3) evaluated core temperature in subjects at rest, and at exercise, in each of hot and cold water, comparing esophageal, rectal thermistor, and radio pill (pills from HTI, and data logger from BBN Systems, Cambridge, MA), temperatures. Similar to others (1), they found that rectal temperatures were generally higher than esophageal temperatures and radio pill temperatures were intermediate.

Core temperature measurement via radio pill has been criticized as producing variability in core temperature as the pill courses through different regions in the gastrointestinal tract (1,2). The temperature fluctuation due to pill movement has been quantified as ranging from 0.2 – 0.3°C (1). This amount of variability is not likely to be of physiological significance for many applications (3).

The work described above (1,2,3,4) has evaluated core temperature measured by radio pill against more traditional methods (rectal and/or esophageal temperatures) over 1 to 3 hours during normal working hours. However, there is very little information as to the efficacy of the radio pill with respect to its ability to accurately track the diurnal temperature trough, which is pre-requisite to successful work in the domain of circadian rhythms. This study is to evaluate the radio pill against the rectal probe during 15 hours including the overnight period in order to determine whether or not the radio pill is sensitive enough to measure the circadian temperature trough.

# METHODS

Our 7 subjects (6 males and one female) ranged from 23 to 51 years of age. All subjects reported to the laboratory at 1500 h on their test day. Before ingestion by the subject, the radio pill was calibrated against a rectal probe in a water bath at 37.0°C. The calibration of the radio pill was confirmed to be within 0.1°C of the rectal probe. The subject then ingested the pill and inserted a rectal probe 15 cm. into the rectum. The data loggers for each of the probe and radio pill were worn on a belt throughout the experimental period. The subjects were instructed to return to the laboratory at 0800 h the next morning. They were also instructed to avoid any strenuous activity and to maintain a log of when and what they ate and drank.

The radio pills were manufactured by Human Technologies (HTI) of St. Petersburg, FL, and because they were the most recent series of their pills (manufactured after January 1997), they had "tighter calibrations" than their prior series of pills. The data logger for the radio pill (BCTM2) was manufactured by Personal Electronic Devices (PED) of Wellesley Hills, MA. Essentially, the PED data logger, which measures approximately 10.75 cm x 8 cm x 3.75 cm, is an improved, more reliable version of the data logger built by BBN systems used by Obrien et al (3).

The rectal probes were manufactured by the Pharmaseal Division, Baxter Health Care of Valencia, CA (Pharmaseal 400 series rectal/esophageal probe). The data logger for the rectal probes was manufactured by ACR of Surrey, BC (Smart Reader Plus 8) and measures approximately 10cm x 7.5cm x 2 cm.

The data loggers for each of the rectal probes and the radio pills were set to collect temperatures every minute. At the end of the experimental period, the core temperature data were downloaded to a computer spreadsheet for analysis. Data from every 15th minute were submitted to a double repeated-measures analysis of variance using Superanova, (Abacus Concepts, Berkeley,CA) with *sensor* (2 levels: probe and pill) and *time* as the repeated measures.

To partition the variability of radio pill output due to any inherent variability of the pill versus variability due to transit through different areas of the GI tract, a pill and a rectal probe were immersed in a water bath at 35°C. The bath was then heated to approximately 39.7°C over more than 3 hours, at which point, the heater was turned off and the water bath allowed to cool passively over almost another 2 hours. These data were downloaded to a computer spreadsheet for analysis.

To assess the impact of drinking fluids on radio pill core temperature, 3 trials were run where 2 subjects drank 250 mL of each of cold water (7.1°C), body temperature water (37.0°C), and hot water (60.0°C) at 2 hour intervals during a 15 hour period. These data were also downloaded to a computer spreadsheet for analysis.

## RESULTS and DISCUSSION

The radio pill variability data from the water bath is plotted in figure 1 and illustrates that the temperature curve from the radio pill is virtually super-imposable over the curve from the rectal probe. The radio pill temperature averages were 0.1°C higher than those of the rectal probe.

This would suggest that there is no apparent variability inherent in the radio pill itself and that there is no real difference in temperature (mean difference = 0.1°C) measured by the radio pill relative to that measured by the rectal probe when they are in the same micro-environment. Further, any radio pill output variability in the gastrointestinal tract of a subject is due exclusively to changes in micro-environment as the pill transits through areas which have varying amounts of vasculature, perfusion and metabolism, and therefore are at slightly different temperatures.

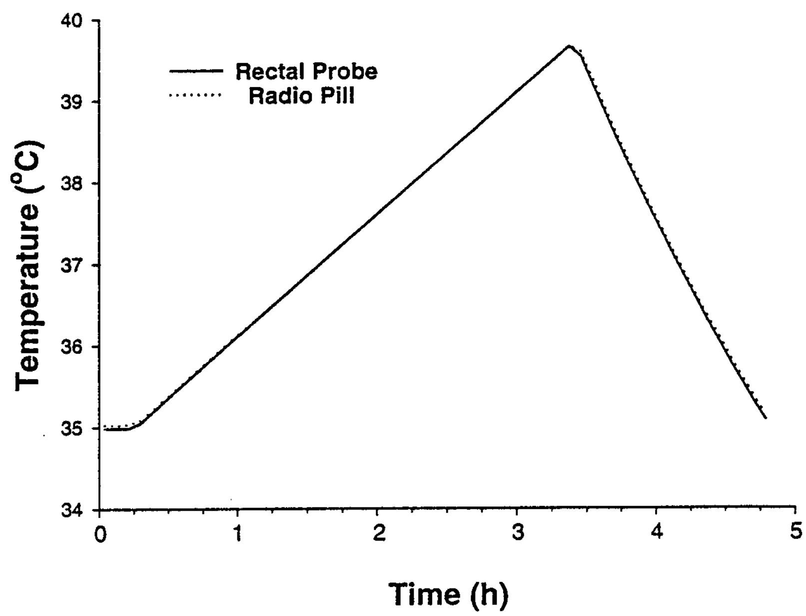


Figure 1. Plot of rectal probe and radio pill temperature curves as water bath is actively heated from 35 to 39.7°C and then allowed to passively cool.

With respect to the comparison of rectal probe and radio pill temperatures across the whole data set of our 7 subjects, the main effect of *sensor* (pill vs. probe) was not significant (p=.633) while the main effect *time* was highly significant (p=.0001). The interaction between *sensor* and *time* (figure 2) was not significant (p=.093).

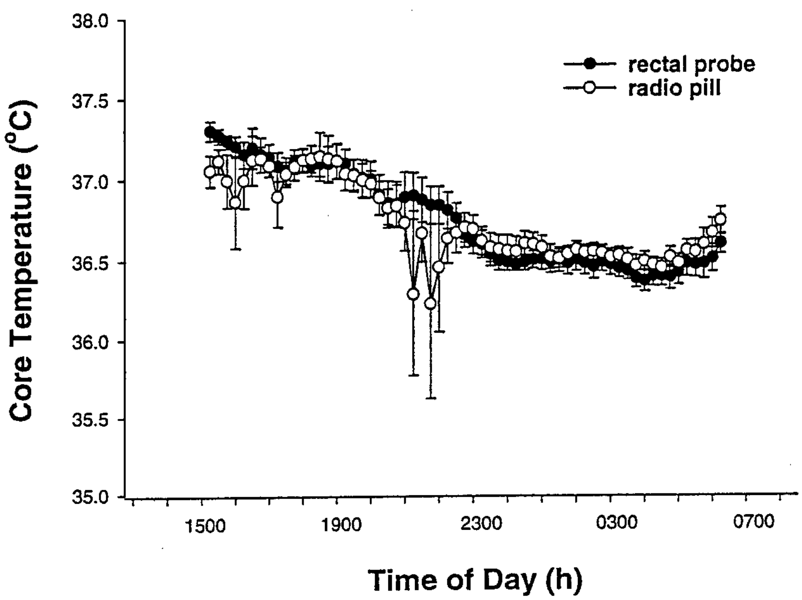


Figure 2. Plot of temperature curves over time for each of the rectal probe and the radio pill trials. The data, from every $15^{th}$ minute are expressed as mean ± S.E. for the 7 subjects.

For the second half of the curves (Figure 2), the temperatures provided by the radio pill are consistently slightly higher than those provided by the rectal probe by an average of 0.08°C. During the first half of the curves, around the supper hours, (approx. 1700 to 1900 h), and just before bedtime (approx. 2130 to 2330 h) the temperatures provided by the radio pill show excursions below the rectal probe curve by about 0.6°C. This is due to the fact that the subjects were drinking cold fluids (water, milk, juice, etc) during those periods. These cold drinks tended to preclude a significant main effect of *sensor,* and to favour a *sensor x time* interaction (p=.093) which could have reached statistical significance if the subjects had drank more cold fluids. Of interest is the fact that if only the data collected after the subjects retire to bed (during which time there is no drinking of cold fluids) is submitted to the analysis of variance, a different statistical picture emerges. Because the radio pill temperatures are consistently slightly above rectal temperatures the main effect of *sensor* approaches statistical significance (p=0.083) as compared to p=0.633 for the whole curve. In this case the main effect of *time* is much less significant (p=0.074) as compared to p=0.001 for the whole curve, because during

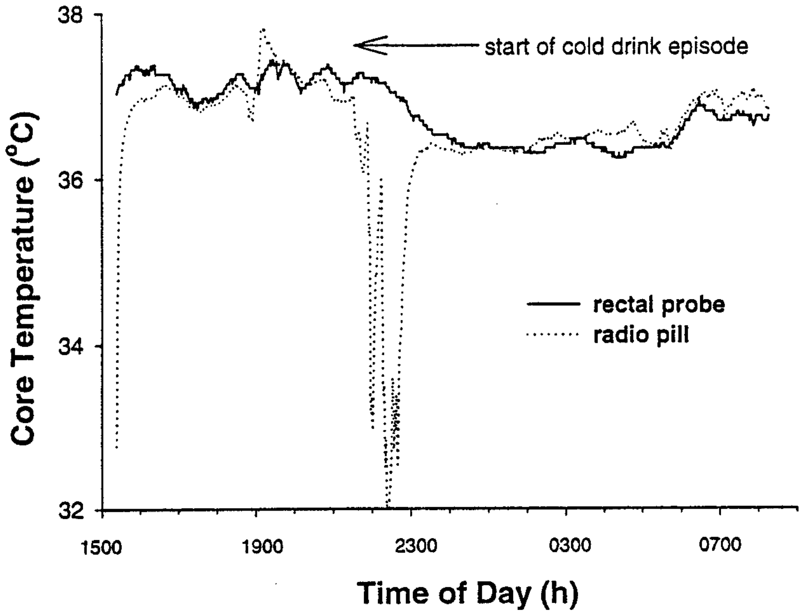


Figure 3. Plot of Core Temperature from Rectal Probe and Radio Pill over Time of Day for Subject 3, showing the impact of cold drinks on Radio Pill Temperature.

this quiet night period (when the circadian temperature trough occurs) the temperatures are uniformly lower than during the earlier part of the data collection (Figure 2). Further, because the radio pill temperatures are consistently slightly higher (approximately 0.1 °C) than the rectal probe temperatures during this later period, the *sensor x time* interaction is very non-significant (p=0.688) as compared to p=0.093 for the whole curve. It is obvious from Figure 2 that the radio pill tracks the circadian temperature trough as well as the rectal probe.

In either case (whether the complete data set is submitted to anova or only the last half of the data is analyzed), the mean temperature difference between the radio pill and the rectal probe is only about 0.08°C. Although this small difference may approach statistical significance if only the last half of the data set is analyzed, it has to all intents and purposes, no physiological significance for most applications.

With respect to the impact of drinking cold fluids on radio pill core temperature, the data from subject 3 (Figure 3) shows that for approximately a 2 hour period, the radio pill core temperature curve was totally compromised by drinking cold juice for an extended episode. The data from Figure 3 indicates that around 2130 h, the subject started a series of about four drinks, about 30 minutes apart. Between each drink, the curve shows a partial recovery towards core temperature but then diverges from the rectal probe curve with each successive drink, recovering somewhat between drinks. Given this data we asked 2 of the subjects (subjects 1 and 5 who participated in the trials from which Figure 2 was produced) to again wear a probe and swallow a radio pill to further evaluate the effect of drinking cold water at about 7°C. These 2 subjects also drank hot water (approximately 60°C), and body temperature water (approximately 37°C).

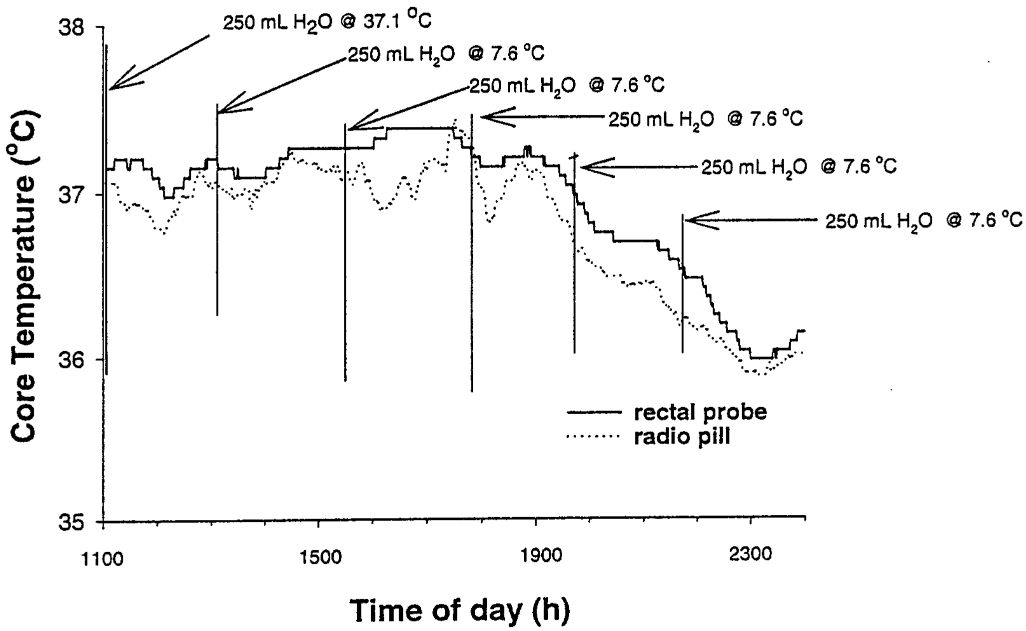


Figure 4. Plot of Core Temperature from Rectal Probe and Radio Pill over Time of Day for subject 1, first water drinking trial, showing the effect of drinking body temperature water and cold water on radio pill temperature.

For subject 1 the effect of drinking cold water as well as body temperature water is illustrated in Figure 4. This figure indicates that subject 1 first ingested one drink of body temperature water, followed by 5 drinks of cold water. Immediately after the body temperature drink, the radio pill temperature is about 0.2°C lower than the corresponding rectal temperature but the slopes of both curves at that point are similar indicating a small decrease in temperature. Since both probes reacted similarly, the effect of the drink is difficult to detect. The first cold drink illustrates that the radio pill and rectal probe temperatures are quite similar in the period immediately following ingestion of that drink. The next two cold drinks indicate that the radio pill temperatures fall away from the rectal probe temperatures for two different periods of time. The last 2 cold drinks show that while the radio pill temperatures are slightly lower than the rectal probe temperatures they are both falling in a similar manner, perhaps more due to the approaching circadian temperature trough than to the cold drinks.

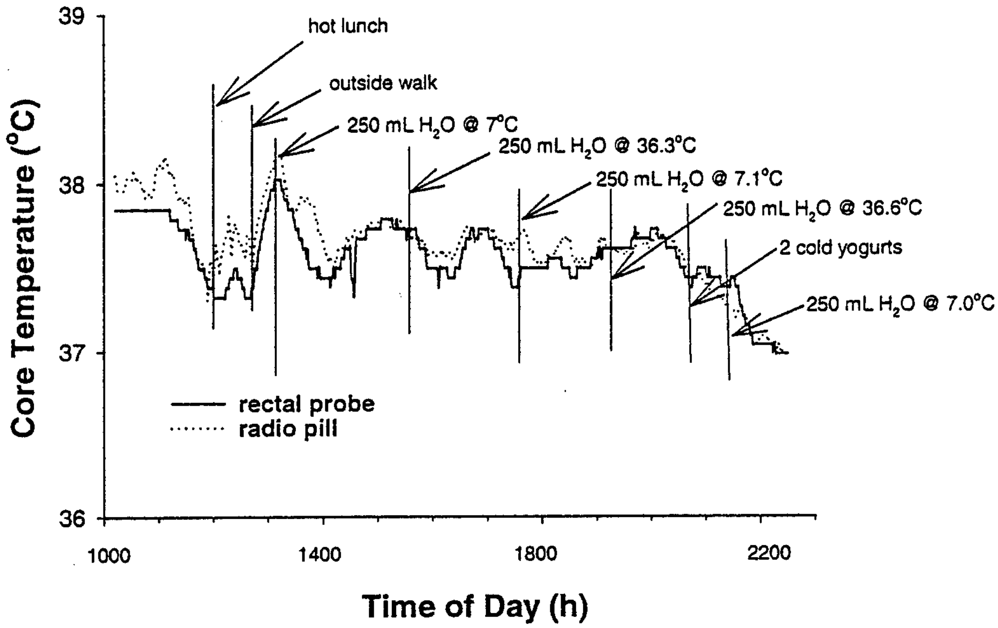


Figure 5. Plot of Core Temperature from Rectal Probe and Radio Pill over Time of Day for Subject 5, showing the effect of drinking body temperature water and cold water on radio pill temperature.

For subject 5, the effect of drinking cold and body temperature water is illustrated in Figure 5. Following a hot lunch (event indicated on Figure 5) this subject went outside for a brisk walk during which core temperature indicated by both the rectal probe and the radio pill increased in a very similar manner. At the end of the walk, this subject consumed a cold drink, after which both the rectal probe and the radio pill temperatures declined. It is not clear whether or not the decline in temperature at this point is due to cooling down after the brisk outside walk, or due to the cold drink, or a combination of these 2 events. Later, around 1530 hrs this subject ingested a body temperature drink which indicates no essential difference between the rectal probe and radio pill temperatures. The cold drink taken by this subject around 1730 hrs indicates a very small decrease in radio pill temperature, down to the level of the rectal probe temperature. The body temperature drink just after 1900 hrs shows no effective separation of the radio pill and rectal temperature curves. Neither the cold yogurts taken around 2030 hrs, nor the cold drink around 2130 hrs, appears to have impacted significantly on radio pill temperature.

Finally, the impact of hot water on radio pill core temperature was also evaluated by subject 1 (Figure 6). At about 0945 hrs, this subject took a drink of body temperature

water which appeared to have no effect on radio pill temperature. The hot drink taken around noon appeared to raise radio pill temperature slightly which recovered to rectal probe values within the hour. What makes this difficult to interpret is that from about 1100 to 1230 hrs the radio pill temperatures appear to be elevated in a similar manner, and for no apparent reason. The hot lunch consumed around 1330 hrs appears to cause a small transient increase in radio pill temperature, while the body temperature drink consumed around 1430 hrs appears to cause a slight drop in radio pill temperature. The hot drink taken around 1630 hrs seems to cause an increase in radio pill temperature of about 0.4 C which slowly falls in parallel with rectal probe temperature over the next 2 hours.

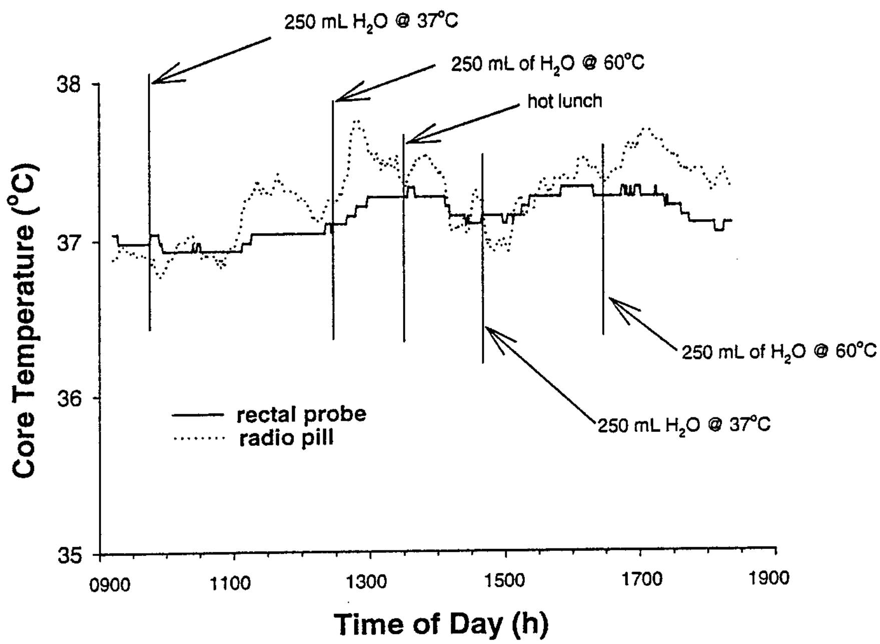


Figure 6. Plot of Core Temperature from Rectal Probe and Radio Pill over Time of Day for Subject 1, showing the effect of drinking body temperature water and hot water on radio pill temperature.

The water drinking episode of subject 3 (Figure 3) alerted us to the potential for uncontrolled drinking of cold water to compromise the recording of core temperature via radio pill. The subsequent efforts to examine this phenomenon by having subjects 1 and 5 drink three temperatures of water (cold, body temperature, and hot) at different times after ingestion of the radio pill have been somewhat inconsistent. While cold water has been demonstrated to cause precipitous drops in core temperature provided by radio pill, it does not always have the same effect. Cold water taken at different times after pill ingestion does not produce systematically consistent results. Nor does hot water. It is apparent that while drinking body temperature water can cause radio pill temperature to rise or fall slightly, the magnitude of the changes in temperature are small and vary from

no change to a small drop of about 0.2°C. Therefore, to protect against disrupting core temperature provided by radio pill, if subjects must drink at all, it would be prudent to limit drinking to small amounts, and then using only body temperature water. Further investigation is needed to clarify the effect of water drinks on radio pill temperature recordings.

## CONCLUSIONS

This latest version of the radio pill core temperature monitor along with the improved radio pills, appears to provide an accurate alternative to rectal probes. Further this radio pill technology is sensitive enough to reliably discriminate the diurnal core temperature trough. However, allowing the subjects to drink either hot or cold drinks can result in measurement errors in core temperature. If subjects must drink during an experimental session, and if it is important to avoid drinking-induced perturbations of core temperature provided by radio pill during such sessions, subjects should only drink body temperature fluids.

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**Introduction.** Previous efforts to record core temperature with radio pills produced consistent results showing that core temperature provided by radio pill tended to be lower than that provided by rectal probe by about 0.5°C to 0.6°C. Part of this temperature difference (about 0.2°C to 0.3°C) was thought to be due to the fact that as the radio pill courses through the gut, it passes through areas of differing vasculature, perfusion, and metabolism which result in slightly varying local core temperatures. The studies which produced these results were generally monitoring subjects for 3 to 4 hours. There was very little information as to the efficacy of the radio pill with respect to its ability to track the daily circadian temperature trough, which is a pre-requisite to successful work in the domain of circadian rhythms. This study is an attempt to evaluate the radio pill against the rectal probe, over 15 hours, in order to determine whether or not the radio pill is sensitive enough to discriminate the circadian temperature trough. **Methods.** Resting core temperatures provided by radio pill and by rectal probe, were monitored in 7 subjects over 15 hours, including the overnight period. The rectal probe and its data logger were the standard units used in this laboratory. The radio pill and its data logger were recently improved units lent to us by their manufacturers for evaluation. The data loggers for each of the rectal probes and the radio pills were set to collect data every minute. The subjects wore the data loggers (for each of the pill and probe) on a belt throughout the 15 hour time block. The data from the 7 subjects were submitted to a double repeated-measures analysis of variance (anova). To partition the variability of radio pill output due to any inherent variability of the pill versus variability due to transit through different areas of the GI tract, a pill and a probe were immersed in a water bath at 35°C. The bath was then heated to approximately 39.7°C over more than 3 hours, at which point, the heater was turned off and the water bath allowed to cool passively over almost another 2 hours. To assess the impact of drinking fluids on radio pill core temperature, several trials were run where 2 subjects drank 250 mL of each of cold water (7.1°C), body temperature water (37.0°C), and hot water (60.0°C).
**Results & Discussion.** The comparison of the radio pill and the rectal probe in the water bath indicate that there is no variability inherent in the radio pill itself and no real difference in temperature measured by the radio pill and the rectal probe when they are in the same micro-environment. The anova for the core temperature data from the 7 subjects indicates there was no main effect of *sensor* (pill vs. probe, $p=0.633$) but the main effect of *time* was significant ($p=0.001$). The *sensor x time* interaction was not significant ($p=0.093$). The main effect of *time* was significant because the night time temperatures (during the circadian trough) were lower than the day time temperatures. While the *sensor x time* interaction was not significant it showed a tendency towards significance because of the drinking-induced drop in radio pill temperature during the supper and early evening hours. It was noted that drinking of either hot or cold drinks can cause gross errors in core temperature as measured by radio pill. **Conclusions.** This latest version of the radio pill core temperature monitor appears to provide an accurate alternative to rectal probes. If subjects must drink during an experimental session, and if it is important to avoid drinking-induced perturbations of core temperature provided by radio pill during such sessions, subjects should only drink body temperature fluids.

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